

ESTABLISHED 1949

# United Trademark & Patent Services

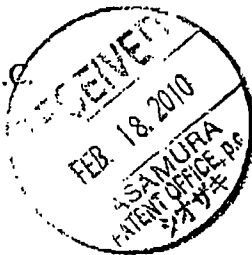
## INTELLECTUAL PROPERTY ATTORNEYS



Also at Karachi & Islamabad  
ATTORNEYS-CONSULTANTS-SOLICITORS  
**PATENTS-DESIGNS-TRADE MARKS**  
COPYRIGHTS & RELATED RIGHTS  
COMPANY LAW-MERCANTILE LAW

A Legal House for the attainment of Patents, Designs, Trade Marks, Copyrights, Trade Contracts & Agreements

Sadafumi Kobori, Esq.,  
Applications Dept.  
ASAMURA PATENT OFFICE, P.C.  
331 New Ohtemachi Bldg. 2-1  
Ohtemachi 2-chome  
Chiyoda-Ku  
Tokyo 100-0004  
Japan.



Y/ref: W1892-26 (3)

O/ref: HIK/YM/HA/139912

別件あり  
(受信係)

Lahore: February 17, 2010

BY FAX : +81-3-3246-1239 / 3270-5076

Extendible DEADLINE – MARCH 6, 2010

Re :: **OPPOSITION to**  
Pakistan Patent No. 139912 (Application No. 1225/2006)  
In the name of: OTSUKA PHARMACEUTICAL CO., LTD  
By  
Pakistan Pharmaceutical Manufacturer's Association (PPMA)

Dear Colleagues,

In connection with the above subject, further to our letter to January 14, 2010, we advise you as a result of our request to issue the letters patent, the patent office has advised us that within the opposition expiry term of September 5, 2009 Pakistan Pharmaceutical Manufacturers Association (hereinafter referred to as PPMA), a body representing generic manufacturers of the country, filed a Notice of Opposition to oppose the above application.

The Notice of Opposition and the Statement in Support of Notice of Opposition have now been served upon us by the Controller and the first extendible deadline is for 6<sup>th</sup> March, 2010. Copies of said documents are enclosed herewith for your record, review and comments.

We have reproduced the grounds below verbatim including the typographical and grammatical errors made by the Opponent.

### Grounds of Opposition

- That this application is obvious in the presence of prior art, Particularly US 5668127; US 5317019; US 6087358; WO/1997/001562A1 and One Paper Published in 1987 by Raj K. Sehgel as the basic molecule was known to the world prior to filing subject Application.
- A process known per se prepares that the Prior art anticipates this application, as what has been claimed in this application.

Cont'd...P/2

#### Postal & Visiting Address:

85 -The Mall Road,  
Lahore 54000 Pakistan  
(Opposite Ferozsons books store /  
adjacent radio time center)

#### Head Office:

West End Building,  
81-The Mall,  
Lahore - 54000  
PAKISTAN.

#### Phones: +92 42 36285571-74

+92 42 36285581-84  
+92 42 36285588-90

Email : UnitedTrademark@UnitedTm.com  
Uttmp@UnitedTm.com

#### Fax +92 42 36285585

+92 42 36285586  
+92 42 36285587  
+92 42 37323501

Website: www.utmps.com

Undertaking: Registrations in South & East Asia, Middle East, Gulf and North African countries through the network of regional offices.

ESTABLISHED 1949



-: 2 :-

ASAMURA PATENT OFFICE, P.C.  
Japan.

Lahore: February 17, 2010

- c) That the invention is not a patentable invention within the meaning of this Ordinance.
- d) That the invention claimed in the claims is not specific but ambiguous in nature as the claims are not definitive. The claims are very wide in nature and scope.
- e) The invention is also objectionable under Section 10 of the Patents Ordinance, 2000
- f) That the grant of Patent, under the circumstances, shall be contrary to law and Public Interest.

While reviewing the enclosed Notice of Opposition as well as the Supporting Statement, you would note that the grounds of Opposition alleged by the PPMA all revolve around the issue of non-patentability i.e. the invention is not novel, is anticipated by prior art and is obvious and thus not patentable. We have carefully analyzed the grounds of Opposition and the Supporting Statement and our comments and opinion regarding these main issues is as follows:

**Our analysis of the grounds of Opposition**

**1. The Opponent.**

1.1 As you may already be aware, PPMA is a body representing the local/national pharmaceutical companies of Pakistan. Many infringement suits have been filed by leading international pharmaceutical companies against various members of PPMA, and it seems that PPMA has started opposing applications of various research based companies for those products which its member companies may have either already launched or may be planning to launch in the future, so that grant of patents for those products or their improvements, are blocked and/or delayed.

1.3 Although under Section 23 of the Patents Ordinance 2000, "any person" may give notice of opposition to the Controller of Patents against the grant of a patent, and "any person" has been defined by the Ordinance to include an "Association" however it is highly doubtful whether an "association of members having no personal interest in the matter or which is not personally effected" would fall under the definition of "any person". There is no precedent under the patent law on this aspect however under general civil and commercial law there are some cases in which the courts of Pakistan have held that an association can not sue in the collective capacity of its members. In other words, when the rights of an individual member of the association are affected then such an individual member of the association must sue or file in his own name, and the association can not file legal proceedings on behalf of its members. We shall therefore challenge the maintainability of the opposition filed by PPMA.

Cont'd...P/3

ESTABLISHED 1949



-: 3 :-

ASAMURA PATENT OFFICE, P.C.  
Japan.

Lahore: February 17, 2010

**2. Issue of maintainability of Opposition on the basis of failure to comply with statutory criteria:**

2.1 In our opinion, under the patent laws of Pakistan, an Opposition can only be based on the grounds prescribed by the provisions of Section 23 of the Patents Ordinance 2000.

2.2 Under Section 23, an Opposition can be filed if the (i) invention is not patentable within the meaning of the Ordinance, (ii) specification does not disclose the invention in clear and complete manner, (iii) claims are not clear and extend beyond the scope of specification and (iv) disclosure of invention is in a manner which prejudices novelty (disclosure prior to the application in question).

2.3 While the ground that "the invention is not a patentable invention within the meaning of the Ordinance" is a very wide ground and can be said to encompass within it, several of the grounds put forth by the PPMA, however, in our opinion, at least the ground (f) in the said Opposition should not be allowed to be raised. Also, the grounds which have been mentioned in the Statement of Case are also not permissible as under Rule 18 of the Patents Rules, 2003 an Opponent can only mention the following in the Statement of Case:

- i) The nature of opponent's interest,
- ii) Facts they rely upon and
- iii) The relief which is being claimed in accordance with the "grounds" of opposition.

2.4 Therefore based on the above, in our counter statement as well as in our arguments before the Controller, we intend to strongly raise the argument that the opposition is not maintainable in law, at least those grounds that mentioned in Form P-7 and the full written statement dated September 03, 2009 which are beyond the scope of the grounds provided by the Patents Ordinance, 2000.

**3. Invention is not patentable because it is Obvious, Lacks an inventive step and is anticipated by Prior Art:**

In grounds (a) and (b) the Opponent has alleged that the invention of the applicant is obvious and has been anticipated based on prior art (US 5668127; US 5317019; US 6087358; WO/1997/001562A1 and One Paper Published in 1987 by Raj K. Sehgel) and is thus non patentable. The Opponent has further alleged that the invention of the applicant is not a patentable invention within the meaning of the Patents Ordinance, 2000. However, the opponent has not mentioned any specific reason and/or description of the invention due to which the subject matter of Patent 139912 is obvious and un-patentable.

In our opinion the above objection is not validly raised due to the following reasons:-

Cont'd...P/4

ESTABLISHED 1949



-: 4 :-

ASAMURA PATENT OFFICE, P.C.  
Japan.

Lahore: February 17, 2010

- i) In terms of the Patents Ordinance, 2000, an invention to be patentable must meet the statutory requirements for patentability namely:
- novelty
  - inventive step (i.e. non-obviousness)
  - industrial applicability
  - Non-exclusion by the statutory exceptions to the grant.

The opponent has just made a blanket statement without specifically indicating how the invention is lacking an inventive step and how it is obvious. The Opponent must establish any "*prior art*" so as to *prima facie* show that the invention covered by the present patent application was in any way obvious to a person skilled in the art prior to its invention by the Applicant, which the Opponent has failed to do. A mere allegation does not make the invention obvious or non patentable and lacking "novelty". Clearly, the Opponent has failed to disclose or show that any person or company prior to the Applicant produced, marketed or started selling a Pharmacologically acceptable salt of 2,3-DIHYDRO-6-Nitroimidazo[2,1-b] Oxazole compound. It is an invention of the Applicant and satisfies the criteria of novelty prescribed by the law on the subject.

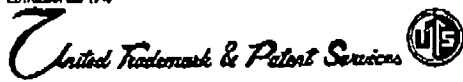
With regard to the patents cited as prior art, similar patents have been disclosed in the current Patent Application by Otsuka International. US 5668127 pertains to Nitroimidazole antibacterial compounds and methods of use thereof; US 5317 019 is a patent for Inhibition of interleukin-1 and tumor necrosis factor production by monocytes and/or macrophages; US 6087385 refers to a patent for Nitro-[2,1-b]imidazopyran compounds and antibacterial uses thereof; WO/1997/001562 also pertains to an invention of new nitroimidazole derivatives which are useful in killing pathogenic microbes. Additionally, the Opponent has simply mentioned an article published in 1987 by Raj.k Sehgel; this in itself is not sufficient. As you are aware, the present invention provides a compound having an excellent bacterial action to Mycobacterium tuberculosis and multi drug resistant Mycobacterium tuberculosis, which is not anticipated by any prior art.

In this respect, we have noted that present application relates to compounds of a general formula 1 and method of producing the same (claims 1 to 35). The compound of the invention can be distinguished from the 2, 3-di-hydro-6-nitroimidazo[2,1-b]oxazole derivatives disclosed in the prior art (compounds having an anti-tubercular activity) by the substitution pattern defined by  $R^1$  and  $(CH_2)_nR^2$  according to the invention represent a very complex group consisting of one ring to which at least another substituted ring moiety is attached, while the side chain or spiro ring in the prior art compounds is of much simple nature. The subject matter of invention is therefore, novel and application No. 860/2004 provide further compounds that are effective and suitable for the treatment of tuberculosis as given in the specification.

In this respect, in our defense we intend to described that 2,3-dihydro-6-

Cont'd...P/5

ESTABLISHED 1949



-: 5 :-

ASAMURA PATENT OFFICE, P.C.  
Japan.

Lahore: February 17, 2010

nitroimidazo[2,1-b]oxazole compounds may be used as antitubercular agent but substitution pattern at the oxazole part of the bi-cyclic ring in the prior art compounds is quite simple as compared to the compound (1) of the application No. 860/2004.

We shall further submit that due to complicated substitution pattern it cannot be considered as obvious to a person skilled in the art. Therefore, an inventive step in terms of Patents Ordinance, 2000 can be acknowledged for the claims of application No. 860/2004.

As Pakistan patent law does provide protection to salt of a compound, recognizes a salt of a compound to be a subject matter of an invention, and claiming of salts is an important aspect for protection of compound, in particular in enforcement proceedings against generics, and as salt of a compound is in fact a new compound, we shall strongly assert in our defense that this ground of opposition is frivolous and without any reasoning.

The Applicant has clearly mentioned all the requisite information in the specification, therefore, the Applicant has not concealed any facts with regard to the prior art from the Controller of Patents or claimed any thing beyond the scope of claims of patent No. 139912. What the Applicant is claiming a Pharmacologically acceptable salt of 2,3-DIHYDRO-6- Nitroimidazo[2,1-b] Oxazole compound, hence, the Opponent's allegations that the invention is the same as prior art are baseless.

Most importantly the Opponent has completely failed to point out any part of the Specification or Claims of the Patent Application which is in any way anticipated and/or disclosed by the above mentioned Patents. Moreover the Opponent has not even made an effort to elaborate on the patents in its Statement that it is alleging anticipate the invention in question. In the absence of any such explanation, the Opponent's objection to Patent No. 139912 on the grounds of anticipation by the above referred prior art is totally baseless, false and frivolous.

In case the Applicant will decide to defend the Opposition we will plead in the counter statement that the subject matter is an invention of the Applicant and satisfies the criteria of patentability prescribed by the law therefore, the invention covered by the Application qualifies for grant of patent.

Any further advice or points in support of the novelty of the invention will be appreciated especially if not already detailed in the specification which we will include in the defense.

4. **The claims are ambiguous as they are wide and not definitive:**

Ground (d) is another vague and irrelevant ground as the claims of patent No. 139912 are

Cont'd...P/6

ESTABLISHED 1949



-: 6 :-

ASAMURA PATENT OFFICE, P.C.  
Japan.

Lahore: February 17, 2010

clear enough to describe the invention and they are fairly based upon the description given in the specification. Clearly, the specification and claims of the Applicant's Patent No. 139912 describe the scope of the invention as well as the manner in which the invention has to be performed.

In this respect we intend to describe in our counter statement that the scope of claims of this patent has already been reduced during prosecution of the application as the claims were restricted to a much narrower definition and the abstract has been amended and made consistent with the claims.

In our opinion, this ground stands negated from clear statutory provisions therefore; it is not likely to be of any help to the Opponent.

5. **Invention is objectionable under Section 10 of the Ordinance.**

That the contents of Ground (e) of the Opposition on Form P-7 apart from being vague and unspecific, are also without any substance particularly on account of Opponent's failure to show how the invention mentioned in the Application has no "industrial application". It is an established principle that if an invention is capable of being manufactured or otherwise industrially used, it shall satisfy the criteria of "industrial application". Hence, the contents of this ground are absolutely nullified and are liable to be rejected by the controller of Patents.

6. **The ground that grant of the patent will be contrary to law and public interest**

In ground (f) the opponent has tried to stretch the issue of "*public interest*" and also tried to equate "*commercial and business interest*" of its members with the "*public interest*". Also opponent has not disclosed how the invention is contrary to law, when it fulfills all the requirements for patentability, or how it is against the public interest. It seems that the Opponent is merely trying to add as many frivolous grounds of opposition as possible without basing them on anything concrete.

The full Written Statement also reiterates the same allegations and matters which have no relevance. In fact they are not even permitted to be raised in an opposition to the grant of a patent.

You will note that in paragraph one of the Written Statement PPMA has indicated its object with a purpose to assert that it is within their scope of activities to file the present opposition. It is, however, interesting to observe that in paragraph 11 they are asserting that their members can not oppose the grant in all cases; therefore, the present opposition has been filed on behalf of the members of the association.

As indicated above we will strongly assert that the opposition can not be filed by the association

Cont'd...P/7

ESTABLISHED 1969



-: 7 :-

ASAMURA PATENT OFFICE, P.C.  
Japan.

Lahore: February 17, 2010

as it has no personal interest in filing the opposition and it would not personally be affected by the grant of a patent. . Even otherwise as per PPMA's own stance in paragraph 11 of the full written statement, it seems to be opposing those applications for which its members' rights are not even affected. This is because PPMA has asserted that "in order to secure protection some of the individual members of the Association have filed opposition to the grant of Patents, where the matter directly affecting their rights, but according to the provision available in the Patents Ordinance 2000 the member cannot oppose the grant of Patent in each and every case. Hence this opposition on behalf of members of that Association," which also shows that PPMA is filing oppositions to those applications for which no member of PPMA has any interest, and therefore the opposition is liable to be dismissed.

Kindly confirm that we may file the counter-statement/defense to the opposition. The current time to do so expires on 6<sup>th</sup> March, 2010 which is extendible on a monthly basis up to a maximum of three months.

We look forward to receive your instructions and remain  
With best regards.

Very truly yours,  
for UNITED TRADEMARK & PATENT SERVICES,



MARIA FARRUKH IRFAN KHAN

\\Vasirshare\Usb\hoda\Report\Report for 139912-Amended.doc

ESTABLISHED 1948

**United Trademark & Patent Services**  
INTELLECTUAL PROPERTY ATTORNEYS

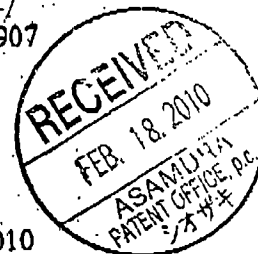


Also at Karachi & Islamabad  
ATTORNEYS-CONSULTANTS-SOLICITORS  
PATENTS-DESIGNS-TRADE MARKS  
COPYRIGHTS & RELATED RIGHTS  
COMPANY LAW-MERCANTILE LAW

A Legal House for the attainment of Patents, Designs, Trade Marks, Copyrights, Trade Contracts & Agreements

Sadafumi Kobori, Esq.,  
Applications Dept.  
ASAMURA PATENT OFFICE, P.C.  
331 New Othomachi Bldg. 2-1  
Ohtomachi 2-chome  
Chiyoda-Ku  
Tokyo 100-0004  
Japan.

Y/ref: W1892-05 C-2  
O/ref: HIK/YM/HA/139907



Lahore: February 17, 2010

BY FAX : +81-3-3246-1239 / 3270-5076

Extendible DEADLINE – MARCH 6, 2010

Re :: **OPPOSITION to**  
Pakistan Patent No. 139907 (Application No. 860/2004)  
In the name of: OTSUKA PHARMACEUTICAL CO., LTD  
By  
Pakistan Pharmaceutical Manufacturer's Association (PPMA)

Dear Colleagues,

In connection with the above subject, further to our letter of January 18, 2010, we advise you as a result of our request to issue the letters patent, the Patent Office has advised us that within the opposition expiry term of September 6, 2009 Pakistan Pharmaceutical Manufacturers Association (hereinafter referred to as PPMA), a body representing generic manufacturers of the country, filed a Notice of Opposition to oppose the above application.

The Notice of Opposition and the Statement in Support of Notice of Opposition have now been served upon us by the Controller and the first extendible deadline is for 6<sup>th</sup> March, 2010. Copies of said documents are enclosed herewith for your record, review and comments.

We have reproduced the grounds below verbatim including the typographical and grammatical errors made by the Opponent.

### Grounds of Opposition

- That this application is obvious in the presence of prior art, Particularly US 5668127; US 5317019; US 6087358; WO/1997/001562A1 and One Paper Published in 1987 by Raj K. Sehgel as the basic molecule was known to the world prior to filing subject Application.
- A process known per se prepares that the Prior art anticipates this application, as what has been claimed in this application.

Cont'd...P/2

Postal & Visiting Address:  
85 -The Mall Road,  
Lahore 54000 Pakistan  
(Opposite Ferozesons books store /  
adjacent rado time center)

Head Office:  
West End Building,  
61-The Mall,  
Lahore - 54000  
PAKISTAN.


Phones: +92 42 36285571-74  
+92 42 36285581-84  
+92 42 36285588-90  
Email : UnitedTrademark@UnitedTm.com  
Utmp@UnitedTm.com

Fax +92 42 36285585  
+92 42 36285586  
+92 42 36285587  
+92 42 37323501  
Website: www.utmps.com

Undertaking: Registrations in South & East Asia, Middle East, Gulf and North African countries through the network of regional offices.



ESTABLISHED 1949

United Trademark & Patent Services 

-: 2 :-

ASAMURA PATENT OFFICE, P.C.  
Japan.

Lahore: February 17, 2010

- c) That the invention is not a patentable invention within the meaning of this Ordinance.
- d) That the invention claimed in the claims is not specific but ambiguous in nature as the claims are not definitive. The claims are very wide in nature and scope.
- e) The invention is also objectionable under Section 10 of the Patents Ordinance, 2000
- f) That the grant of Patent, under the circumstances, shall be contrary to law and Public Interest.

While reviewing the enclosed Notice of Opposition as well as the Supporting Statement, you would note that the grounds of Opposition alleged by the PPMA all revolve around the issue of non-patentability i.e. the invention is not novel, is anticipated by prior art and is obvious and thus not patentable. We have carefully analyzed the grounds of Opposition and the Supporting Statement and our comments and opinion regarding these main issues is as follows:

**Our analysis of the grounds of Opposition**

**1. The Opponent.**

1.1 As you may already be aware, PPMA is a body representing the local/national pharmaceutical companies of Pakistan. Many infringement suits have been filed by leading international pharmaceutical companies against various members of PPMA, and it seems that PPMA has started opposing applications of various research based companies for those products which its member companies may have either already launched or may be planning to launch in the future, so that grant of patents for those products or their improvements, are blocked and/or delayed.

1.3 Although under Section 23 of the Patents Ordinance 2000, "any person" may give notice of opposition to the Controller of Patents against the grant of a patent, and "any person" has been defined by the Ordinance to include an "Association" however it is highly doubtful whether an "association of members having no personal interest in the matter or which is not personally effected" would fall under the definition of "any person". There is no precedent under the patent law on this aspect however under general civil and commercial law there are some cases in which the courts of Pakistan have held that an association can not sue in the collective capacity of its members. In other words, when the rights of an individual member of the association are affected then such an individual member of the association must sue or file in his own name, and the association can not file legal proceedings on behalf of its members. We shall therefore challenge the maintainability of the opposition filed by PPMA.

Cont'd...P/3

ESTABLISHED 1949



- 3 -

ASAMURA PATENT OFFICE, P.C.  
Japan.

Lahore: February 17, 2010

**2. Issue of maintainability of Opposition on the basis of failure to comply with statutory criteria:**

2.1 In our opinion, under the patent laws of Pakistan, an Opposition can only be based on the grounds prescribed by the provisions of Section 23 of the Patents Ordinance 2000.

2.2 Under Section 23, an Opposition can be filed if the (i) invention is not patentable within the meaning of the Ordinance, (ii) specification does not disclose the invention in clear and complete manner, (iii) claims are not clear and extend beyond the scope of specification and (iv) disclosure of invention is in a manner which prejudices novelty (disclosure prior to the application in question).

2.3 While the ground that "the invention is not a patentable invention within the meaning of the Ordinance" is a very wide ground and can be said to encompass within it, several of the grounds put forth by the PPMA, however, in our opinion, at least the ground (f) in the said Opposition should not be allowed to be raised. Also, the grounds which have been mentioned in the Statement of Case are also not permissible as under Rule 18 of the Patents Rules, 2003 an Opponent can only mention the following in the Statement of Case:

- i) The nature of opponent's interest,
- ii) Facts they rely upon and
- iii) The relief which is being claimed in accordance with the "grounds" of opposition.

2.4 Therefore based on the above, in our counter statement as well as in our arguments before the Controller, we intend to strongly raise the argument that the opposition is not maintainable in law, at least those grounds that mentioned in Form P-7 and the full written statement dated September 03, 2009 which are beyond the scope of the grounds provided by the Patents Ordinance, 2000.

**3. Invention is not patentable because it is Obvious, Lacks an inventive step and is anticipated by Prior Art:**

In grounds (a) and (b) the Opponent has alleged that the invention of the applicant is obvious and has been anticipated based on prior art (US 5668127; US 5317019; US 6087358; WO/1997/001562A1 and One Paper Published in 1987 by Raj K. Sehgal) and is thus non patentable. The Opponent has further alleged that the invention of the applicant is not a patentable invention within the meaning of the Patents Ordinance, 2000. However, the opponent has not mentioned any specific reason and/or description of the invention due to which the subject matter of Patent 139907 is obvious and un-patentable.

In our opinion the above objection is not validly raised due to the following reasons:-

Cont'd...P/4

ESTABLISHED 1949



- 4 -

ASAMURA PATENT OFFICE, P.C.  
Japan.

Lahore: February 17, 2010

- i) In terms of the Patents Ordinance, 2000, an invention to be patentable must meet the statutory requirements for patentability namely:
- novelty
  - inventive step (i.e. non-obviousness)
  - industrial applicability
  - Non-exclusion by the statutory exceptions to the grant.

The opponent has just made a blanket statement without specifically indicating how the invention is lacking an inventive step and how it is obvious. The Opponent must establish any "*prior art*" so as to prima facie show that the invention covered by the present patent application was in any way obvious to a person skilled in the art prior to its invention by the Applicant, which the Opponent has failed to do. A mere allegation does not make the invention obvious or non patentable and lacking "novelty". Clearly, the Opponent has failed to disclose or show that any person or company prior to the Applicant produced, marketed or started selling 2,3-DIHYDRO-6- Nitroimidazo[2,1-b] Oxazole compound. It is an invention of the Applicant and satisfies the criteria of novelty prescribed by the law on the subject.

With regard to the patents cited as prior art, similar patents have been disclosed in the current Patent Application by Otsuka International. US 5668127 pertains to Nitroimidazole antibacterial compounds and methods of use thereof; US 5317 019 is a patent for Inhibition of interleukin-1 and tumor necrosis factor production by monocytes and/or macrophages; US 6087385 refers to a patent for Nitro-[2,1-b]imidazopyran compounds and antibacterial uses thereof; WO/1997/001562 also pertains to an invention of new nitroimidazole derivatives which are useful in killing pathogenic microbes. Additionally, the Opponent has simply mentioned an article published in 1987 by Raj.k Schgel; this in itself is not sufficient. As you are aware, the present invention provides a compound having an excellent bacterial action to Mycobacterium tuberculosis and multi drug resistant Mycobacterium tuberculosis, which is not anticipated by any prior art.

In this respect, we have noted that present application relates to compounds of a general formula 1 and method of producing the same (claims 1 to 35). The compound of the invention can be distinguished from the 2, 3-di-hydro-6-nitroamidazo[2,1-b]oxazole derivatives disclosed in the prior art (compounds having an anti-tubercular activity) by the substitution pattern defined by  $R^1$  and  $(CH_2)_nR^2$  according to the invention represent a very complex group consisting of one ring to which at least another substituted ring moiety is attached, while the side chain or spiro ring in the prior art compounds is of much simple nature. The subject matter of invention is therefore, novel and application No. 860/2004 provide further compounds that are effective and suitable for the treatment of tuberculosis as given in the specification.

In this respect, in our defense we intend to described that 2,3-dihydro-6-nitroimidazo[2,1-

Cont'd...P/5

ESTABLISHED 1949



-: 5 :-

ASAMURA PATENT OFFICE, P.C.  
Japan.

Lahore: February 17, 2010

b]oxazole compounds may be used as antitubercular agent but substitution pattern at the oxazole part of the bi-cyclic ring in the prior art compounds is quite simple as compared to the compound (1) of the application No. 860/2004.

We shall further submit that due to complicated substitution pattern it cannot be considered as obvious to a person skilled in the art. Therefore, an inventive step in terms of Patents Ordinance, 2000 can be acknowledged for the claims of application No. 860/2004.

The Applicant has clearly mentioned all the requisite information in the specification, therefore, the Applicant has not concealed any facts with regard to the prior art from the Controller of Patents or claimed any thing beyond the scope of claims of patent No.139907. What the Applicant is claiming a 2,3-DIHYDRO-6- Nitroimidazo[2,1-b] Oxazole compound, hence, the Opponents allegations that the invention is the same as prior art are baseless.

Most importantly the Opponent has completely failed to point out any part of the Specification or Claims of the Patent Application which is in any way anticipated and/or disclosed by the above mentioned Patents. Moreover the Opponent has not even made an effort to elaborate on the patents in its Statement that it is alleging anticipate the invention in question. In the absence of any such explanation, the Opponent's objection to Patent No. 139907 on the grounds of anticipation by the above referred prior art is totally baseless, false and frivolous.

In case the Applicant will decide to defend the Opposition we will plead in the counter statement that the subject matter is an invention of the Applicant and satisfies the criteria of patentability prescribed by the law therefore, the invention covered by the Application qualifies for grant of patent.

Any further advice or points in support of the novelty of the invention will be appreciated especially if not already detailed in the specification which we will include in the defense.

4. **The claims are ambiguous as they are wide and not definitive:**

Ground (d) is another vague and irrelevant ground as the claims of patent No. 139907 are clear enough to describe the invention and they are fairly based upon the description given in the specification. Clearly, the specification and claims of the Applicant's Patent No. 139907 describe the scope of the invention as well as the manner in which the invention has to be performed.

In this respect we intend to describe in our counter statement that the scope of claims of this patent has already been reduced during prosecution of the application as the claims were restricted to a much narrower definition and the abstract has been amended and made consistent with the claims.

Cont'd...P/6

ESTABLISHED 1949



-: 6 :-

ASAMURA PATENT OFFICE, P.C.  
Japan.

Lahore: February 17, 2010

In our opinion, this ground stands negated from clear statutory provisions therefore; it is not likely to be of any help to the Opponent.

5. **Invention is objectionable under Section 10 of the Ordinance.**

That the contents of Ground (e) of the Opposition on Form P-7 apart from being vague and unspecific, are also without any substance particularly on account of Opponent's failure to show how the invention mentioned in the Application has no "industrial application". It is an established principle that if an invention is capable of being manufactured or otherwise industrially used, it shall satisfy the criteria of "industrial application". Hence, the contents of this ground are absolutely nullified and are liable to be rejected by the controller of Patents.

6. **The ground that grant of the patent will be contrary to law and public interest**

In ground (f) the opponent has tried to stretch the issue of "*public interest*" and also tried to equate "*commercial and business interest*" of its members with the "*public interest*". Also opponent has not disclosed how the invention is contrary to law, when it fulfills all the requirements for patentability, or how it is against the public interest. It seems that the Opponent is merely trying to add as many frivolous grounds of opposition as possible without basing them on anything concrete.

The full Written Statement also reiterates the same allegations and matters which have no relevance. In fact they are not even permitted to be raised in an opposition to the grant of a patent.

You will note that in paragraph one of the Written Statement PPMA has indicated its object with a purpose to assert that it is within their scope of activities to file the present opposition. It is, however, interesting to observe that in paragraph 11 they are asserting that their members can not oppose the grant in all cases; therefore, the present opposition has been filed on behalf of the members of the association.

As indicated above we will strongly assert that the opposition can not be filed by the association as it has no personal interest in filing the opposition and it would not personally be affected by the grant of a patent. Even otherwise as per PPMA's own stance in paragraph 11 of the full written statement, it seems to be opposing those applications for which its members' rights are not even affected. This is because PPMA has asserted that "in order to secure protection some of the individual members of the Association have filed opposition to the grant of Patents, where the matter directly affecting their rights, but according to the provision available in the Patents Ordinance 2000 the member cannot oppose the grant of Patent in each and every case. Hence this opposition on behalf of members of that Association," which also shows that PPMA is filing oppositions to those applications for which no member of PPMA has any interest, and therefore the opposition is liable to be dismissed.

Cont'd. P/7

ESTABLISHED 1949



-: 7 :-

ASAMURA PATENT OFFICE, P.C.  
Japan.

Lahore: February 17, 2010

Kindly confirm that we may file the counter-statement/defense to the opposition. The current time to do so expires on 6<sup>th</sup> March, 2010 which is extendible on a monthly basis up to a maximum of three months.

We look forward to receive your instructions and remain,

With best regards.

Very truly yours,  
for UNITED TRADEMARK & PATENT SERVICES,

MARIA FARRUKH IRFAN KHAN

IDS Form PTO/SB/08: Substitute for form 1449A/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)				<b>Complete if Known    CORRECTED</b>	
				Application Number	
				Filing Date	
				April 5, 2006	
				First Named Inventor	
				Hidetsugu TSUBOUCHI	
Art Unit					
Examiner Name					
Attorney Docket Number		01197.0268			
Sheet	1	of	1		

U.S. PATENTS AND PUBLISHED U.S. PATENT APPLICATIONS					
Examiner Initials	Cite No. <sup>1</sup>	Document Number	Issue or Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
		US-			
		US-			
		US-			
		US-			
		US-			

**Note:** Copies of the U.S. Patent Documents are not Required in IDS filed after October 21, 2004

FOREIGN PATENT DOCUMENTS						
Examiner Initials	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Translation <sup>6</sup>
		Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)				
ES		WO-2004/035547 A1	04-29-2004	OTSUKA PHARMACEUTICAL CO., LTD.		Abstract
ES		WO-2004-033463 A1	04-22-2004	OTSUKA PHARMACEUTICAL CO., LTD.		Abstract
ES		WO 97/01562	01-16-1997	PATHOGENESIS CORPORATION		

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Translation <sup>6</sup>
ES		NAGARAJAN et al.; "NITROIMIDAZOLES XXI 2,3-DIHYDRO-6-NITROIMIDAZO [2,1-b] OXAZOLES WITH ANTITUBERCULAR ACTIVITY"; Eur. J. Med. Chem., Vol. 24, pages 631-633, (1989)	
ES		STOVER et al.; "A SMALL-MOLECULE NITROIMIDAZOPYRAN DRUG CANDIDATE FOR THE TREATMENT OF TUBERCULOSIS"; Nature, Vol. 405, pages 962-966, (2000)	
ES		SEHGAL et al.; "POTENTIAL RADIOSENSITIZING AGENT. 2. SYNTHESIS AND BIOLOGICAL ACTIVITY OF DERIVATIVES OF DINITROIMIDAZOLE WITH OXIRANES"; J. Med. Chem., Vol. 24, pages 601-604, (1981)	
ES		ASHTEKAR et al.; "IN VITRO AND IN VIVO ACTIVITIES OF THE NITROIMIDAZOLE CGI 17341 AGAINST MYCOBACTERIUM TUBERCULOSIS"; Antimicrobial Agents and Chemotherapy, Vol. 37, No. 2, pages 183- 186, (1993)	

Examiner Signature	E. Sackey	Date Considered	11/02/11
-----------------------	-----------	--------------------	----------

**EXAMINER:** Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.